REMARKS

This document is filed in reply to the Final Office Action dated December 21, 2005 ("Office Action"). Applicants have filed herewith a Request for Continued Examination and an Information Disclosure Statement.

At the Examiner's request, Applicants have amended the specification to delete an embedded hyperlink and have amended claims 1, 2, 20, and 24 to promote clarity. No new matter has been introduced.

Claims 1-31 are pending. Claims 9-19 and 28-31 have been withdrawn from further consideration as drawn to non-elected inventions. Claims 1-8 and 20-27 are now under examination. Reconsideration of this application is requested in view of the following remarks.

Objections to Specification and Claims

The Examiner objected to the specification for containing an embedded hyperlink. See the Office Action, page 2, lines 7-10. Applicants have deleted the hyperlink.

The Examiner also objected to claims 20-23 for containing an informality. See the Office Action, page 2, lines 12-17. Applicants have corrected the informality at the Examiner's suggestion.

In view of the above amendments, Applicants submit that the objections should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-8 and 20-27 for indefiniteness. Prior to the present amendment, each of claims 1, 2, 20, and 24 recited the phrase "any one of SEQ ID NOs:2, 4, and 17." According to the Examiner, the word "and" should be replaced with "or" in order to make sense grammatically. See the Office Action, page 3, lines 7-11.

Applicants disagree that the original language "does not make sense grammatically," and also disagree that the Examiner's proposed alternative would be an improvement. However, the issue is moot in view of the present amendments to these claims substituting simpler language for the language at issue. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 101

Claims 1-8 and 20-27 stand rejected for lack of utility. Independent claim 1 is drawn to an isolated nucleic acid containing a sequence that encodes a protein comprising the sequence of SEQ ID NO: 2, 4, or 17. According to the Examiner, the claimed invention lacks patentable utility. See the Office Action, page 3, lines 15-16. The basis for this rejection is set forth at pages 3-8 of the Office Action. Applicants respectfully traverse the rejection.

The US Patent and Trademark Office has issued Revised Interim Utility Guidelines Training Materials ("Utility Training Materials") to instruct Examiners on how to interpret and apply the Utility Guidelines to pending claims. The utility requirement is satisfied if either (i) an Applicant has asserted a utility that is specific, substantial and credible, or (ii) the claimed invention has a well-established utility that is specific, substantial and credible (*see* Utility Training Materials at page 9). As discussed below, the invention of the present application satisfies the utility requirement under both prongs. Applicants' specification asserts that the invention has at least one utility that is specific, substantial and credible; in addition, the invention has a well-established utility. The claimed invention, therefore, amply satisfies the utility requirements of 35 U.S.C. § 101. Applicants first address the utilities asserted in the specification.

I. Asserted Utility

Specific Utility

The Utility Training Materials (at page 5) defines "specific" utility as a "utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention." Here, the claimed nucleic acids encode, and therefore can be used to make, polypeptides comprising SEQ ID NOs: 2, 4, and 17 (NR10.1, NR10.2, and NR10.3, respectively). According to the specification, each polypeptide is a hemopoietin receptor protein that binds to a hematopoietin factor. See, e.g., page 3, lines 5-9; and page 8, line 11. The specification asserts, at page 8, line 30, to page 9, line 2, that

> soluble proteins comprising the extracellular domain of NR10 protein and the splice variant of NR10, NR10.2, may be used as a decoy-type receptor to inhibit the NR10

> ligand. They may be useful for treatment of diseases in which NR10 is implicated, such as leukemia. (emphasis added)

Further, the specification, at page 56, line 29 through page 57, line 23, notes that such decoy-type receptors or other inhibitors identified using NR10 as a screening tool, e.g., "specific antibodies that can inhibit the molecular function of NR10," can be used to suppress, e.g., inflammation or allergies.

None of the above asserted utilities can be said to be applicable to a general class of polypeptides. Indeed, not just any polypeptide could be used to inhibit the NR10 ligand, and one of skill in the art would certainly not expect that all polypeptides could be used to treat an NR10-related disease such as leukemia, inflammation, or allergy. Rather, the asserted utility relates specifically to polypeptides that may be used as decoy-type receptors or as antigens to raise specific neutralization antibodies to inhibit a specific ligand, *i.e.*, the NR10 ligand, and the function of NR10. Further, the polypeptides are described as being useful for the treatment of a disease, but not just any disease: a disease in which NR10 is implicated, such as leukemia, inflammation, or allergy. This asserted utility is unquestionably specific.

Further support for concluding that Applicants' asserted utility is specific can be found within Example 3 of the Utility Training Materials, which analyzes the specificity of a utility asserted for a therapeutic protein. In that example:

> The specification discloses a protein having the amino acid sequence of SEQ ID NO: 1 and discloses that the protein can be made by protein synthesis techniques well known in the art. The only disclosed utility for the protein is for curing Alzheimer's disease. There is no other disclosure of any chemical, physical, or biological properties of the protein. There are 98 pages of specification which disclose alternate administration techniques and dosages that are very specific, conventional techniques for protein administration. There are no working examples that demonstrate the specifically asserted utility (at page 27).

Claim 1 in Example 3 of the Utility Training Materials recites "[t]he isolated protein consisting of the amino acid sequence set forth in SEQ ID NO: 1" (at page 27). The Utility Training Materials identifies the asserted utility of the claimed protein as "curing Alzheimer's disease" (at

page 28). In answering whether this asserted utility is specific, the Utility Training Materials states that "[c]uring Alzheimer's disease, a well-known disease, clearly defines a use that depends upon the particular protein disclosed. Therefore, the utility is specific" (at page 28).

As discussed above, Applicants have asserted that the polypeptides encoded by the claimed nucleic acids are useful in treating diseases in which NR10 is implicated, such as leukemia, inflammation, and allergy. Each disease, just as Alzheimer's disease, is a well-known disease. And, just as in Example 3, the asserted utility of the polypeptides encoded by the claimed nucleic acids of the present application "clearly defines a use that depends upon" the polypeptides, *i.e.*, using the polypeptides to inhibit the NR10 ligand and treat leukemia, inflammation, or allergy. Thus, the conclusion that the asserted utility for the polypeptides is specific is consistent with the Utility Training Materials. Accordingly, Applicants have asserted a utility that is specific for the polypeptides, as well as the nucleic acids encoding them.

This asserted utility also meets the MPEP's definition of what would constitute a specific utility:

> Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound....Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, ... (MPEP 2107.01IA, emphasis added).

Applicants have asserted a utility for the claimed nucleic acids that clearly falls within the latter category. As discussed above, the claimed nucleic acids encode polypeptides that are useful for the treatment of diseases in which NR10 is implicated, such as leukemia, inflammation, and allergy. This asserted utility certainly cannot be categorized as one of treating "unspecified disorders," nor as merely a nonspecific "useful biological" activity. Thus, Applicants have

asserted a specific utility for the claimed nucleic acids, in accordance with both the Utility Training Materials and the MPEP.

The Examiner, however, disagrees.

The Examiner states that there is no specific utility, because "[e]ach of these claims is purely speculative in nature with no evidence of record to support any of these asserted utilities" and "there also has been no identification as to why NR10 would have a specific function." See the Office Action at page 4, lines 6-7, and page 7, lines 13-14. Applicants respectfully disagree with the Examiner for two reasons.

First, Applicants previously submitted with the response filed on September 14, 2005 copies of three articles: Dillon *et al.*, Nature Immunology 5(7):752-760, July 2004; Diveu *et al.*, J. Biol. Chem. 278(50):49850-49859, December 12, 2003; and Kernebeck *et al.* Protein Science 8(1):5-12, 1999.

Dillon *et al.* proves that NR10.1, NR10.2, and NR10.3 are receptors of cytokines, e.g., IL-31. Specifically, it teaches that the sequence of NR10.3 (SEQ ID NO: 17) is identical to that of a receptor of Interleukin 31 (IL-31), IL-31 RA variant 4 (IL-31RAV4). See the Abstract, and page 753, right column, second paragraph. The sequence of IL-31-RA and its alignment against SEQ ID NO: 17 were attached to the previous response. Since NR10.3 and NR10.1 have the same extracellular domain and NR10.2 is a splice variant of NR10.1 that lacks transmembrane and intercellular domains but contains the same extracellular domain as NR10.1 and NR10.2, IL-31 is also a ligand of NR10.1 or NR10.2. Dillon *et al.* further describes transgenic mice that over-express IL-31, as well as non-transgenic mice to whom purified IL-31 was administered. The mice exhibited a phenotype that mimics inflammatory disease and allergy. See, e.g., page 755, right column, through page 757. The IL-31 was shown to be acting via IL-31-RA (page 757, columns 1-2, carryover paragraph).

Diveu *et al.* describes another IL-31 receptor A named GPL, the sequence of which is substantially identical to NR10. According to Diveu *et al.*, expression of GPL is induced by INFγ in monocytes and dendritic cells, suggesting that IL-31 and GPL are involved in inflammatory diseases. See page 49854, right column, lines 9-25.

Kernebeck *et al.* describes a family of cytokine receptors and domains conserved among its members. Some of the domains appear in the NR10 polypeptides.

These three articles clearly provide "record to support ... these asserted utilities [in treating inflammation and allergy]" and "there also has been ... identification as to why NR10 would have a specific function [i.e., as a receptor to cytokine IL-31]." As the Dillon and Diveu articles illustrate that the specification accurately characterized the activity and potential utilities of the proteins encoded by the presently claimed nucleic acids, Applicants object to the Examiner's dismissal of them as "irrelevant." They are certainly relevant.

Second, Applicants disagree with the Examiner's characterization of the standard for specific utility. Even if the Examiner were correct in his belief that more evidence is needed to determine the specific functions of NR10, and that the functions have not been unambiguously identified (which Applicants do not concede), that does not mean that Applicants' asserted utility is not "specific."

Again, Applicants refer to Example 3 of the Utility Training Materials. In that example, the only function for the claimed protein described in the specification was the use in curing Alzheimer's disease. The specification did not describe "any chemical, physical, or biological properties" or functions of the claimed protein. *The conclusion that the asserted utility was specific did not depend on the disclosure of any identified function of the claimed protein independent of the asserted utility.* Rather, as discussed above, the utility of curing Alzheimer's disease was deemed to be specific, even though the specification did not describe any other properties or functions. Thus, just as with the asserted utility in Example 3 of the Utility Training Materials, Applicants' asserted utility for the claimed nucleic acids is also specific.

The above-quoted language from pages 4 and 7 of the Office Action makes it clear that the Examiner is concerned with the quality of proof provided in the specification. However, such proof is not relevant to determining whether an asserted utility is specific. If at all relevant to the utility requirement, it would pertain to assessing the credibility of an asserted utility. Accordingly, Applicants will address this aspect of the rejection below under "*Credible Utility.*"

Substantial Utility

The second requirement for an asserted utility is that the invention must have a substantial utility. The Utility Training Materials defines a "substantial" utility as "a utility that defines a 'real world' use" (at page 6). As discussed above, Applicants have asserted that the polypeptides encoded by the claimed nucleic acids have a substantial utility in the treatment (or in screening assays for identifying inhibitors, e.g., specific antibodies, for use in treatment) of diseases such as leukemia, inflammation, and allergy. The treatment of each of these diseases is not insubstantial. Indeed, the Utility Training Materials acknowledges that although treatment of an unspecified disease may not be considered "substantial", the "general rule [is] that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101" (Utility Training Materials at page 6). Here, Applicants have asserted a utility related to specific diseases, *i.e.*, leukemia, inflammation, or allergy. As such, this asserted utility is substantial.

Applicants again refer to Example 3 of the Utility Training Materials, in which the only asserted utility for the claimed protein was curing Alzheimer's disease (*see* page 28). As stated in the Utility Training Materials, "Since a cure for Alzheimer's disease is a desirable outcome based upon a need in the art, the disclosed use of the claimed protein is substantial and 'real world'" (at page 28, emphasis added). In Example 3, the specification did not show any correlation between Alzheimer's disease and a change in the amount or activity of the claimed protein. It provided the amino acid sequence of the protein and merely asserted that curing Alzheimer's disease was a utility for the protein (*see* page 27). This was considered adequate for meeting both the "specific" and the "substantial" aspects of the utility requirement. By analogy with Example 3 of the Utility Training Materials, the asserted utility for the claimed nucleic acids is substantial.

For the above reasons, Applicants respectfully submit that the asserted utility for the claimed nucleic acids is substantial.

Credible Utility

As mentioned above, although the Examiner has explicitly worded the rejection as based on a lack of "specific" and "substantial" utility, it appears that the Examiner may have meant to

challenge the asserted utility under the "credibility" aspect of an asserted utility. Indeed, several of the Examiner's statements are directed to what is alleged to be lack of evidence regarding the function of the claimed nucleic acids or the polypeptides encoded thereby. For example, the Examiner states (emphasis added in each quote):

> [A]ll [asserted utilities] are presented in a prophetic fashion, confirming that at the time of filing the applicants did not yet have any concrete evidence regarding a specific utility for NR10 (Office Action at page 6, lines 12-15).
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> * * *
>
> [T]here also has been no identification as to why NR10 would have a specific function (Office Action at page 7, lines 13-14).
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> * * *
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> The specification fails to establish any evidence that NR10 is associated with any disease state or immune function. Absent this evidence, there is no way to ascertain from the specification what utility may be ascribed to NR10 (Office Action at page 8, lines 7-9).

Each of these statements makes it clear that the Examiner is concerned with whether the claimed invention will actually function as asserted in the specification, *i.e.*, he is challenging the credibility of the asserted utility. Applicants submit that the Examiner has not even begun to meet his burden of establishing that the asserted utility lacks credibility.

The Utility Training Materials makes it clear that very few asserted utilities will fail to qualify as "credible":

> Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use (at page 5).

And, according to MPEP 2107.02IV:

> Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the application for the claimed invention (emphasis added).

With respect to the present application, the Examiner has not established that the logic underlying the asserted utility (*e.g.*, as decoy-type receptors to inhibit the NR10 ligand, and as screening tools to identify therapeutic antibodies for the treatment of diseases in which NR10 is implicated, such as inflammation or allergy) is "seriously flawed," nor that the facts upon which the assertions are based are "inconsistent with the logic underlying the assertion." Nor has the Examiner established that it is more likely than not that a person skilled in the art would not consider credible the asserted specific and substantial utilities. As discussed in detail below, the asserted specific and substantial utilities are indeed credible.

First, Applicants used several art-recognized methods to identify and clone the NR10 gene and to collect various other data that ultimately support the identification of NR10 as a hemopoietin receptor. The art-recognized methods included database searching using sequence homology followed by rational design of oligonucleotide primers for use in nucleic acid amplification and cloning procedures. The database searching included a search for an amino acid sequence fragment similar to fragments from known hemopoietin receptor proteins, wherein the fragment included the YR and WS motifs. The identified NR10.1 amino acid sequence (SEQ ID NO:2) contains conserved cysteine residues, a YR motif, a PP-W motif, a WS motif, and a PXP motif, all hallmarks of the hemopoietin receptor family (*see* the specification at page 3, lines 20-27, and page 46, lines 6-24). Collectively, these structures are characteristic of the extracellular domain of hemopoietin receptor family members.

Based on structural analysis, Applicants identified a soluble hemopoietin receptor protein (NR10.2) and two proteins that contain putative transmembrane domains but differ in the lengths of their putative intracellular domains (NR10.1 and NR10.3) (*see, e.g.*, the specification at page 6, line 29 to page 7, line 4; and page 7, lines 11-22). These structural features are consistent with the NR10 gene's encoding members of the hemopoietin receptor family.

Second, Applicants characterized the tissue distribution of NR10.1 by RT-PCR of RNA isolated from a variety of tissues. Expression of NR10.1 was found to be restricted to specific organs and tissues, and expression "was mainly detected in those organs containing immune responsible cells and hematopoietic cells ..." (*see* specification at page 48, lines 8-9). In view of the expression pattern, one of ordinary skill in the art would conclude it is highly likely that NR10.1 indeed is a member of the hemopoietin receptor protein family.

Given the structure similarities among NR10.1, NR10.2, and NR10.3, one of ordinary skill would also conclude it is highly likely that all three are members of the hemopoietin receptor protein family. Indeed, given these disclosed characteristics, it is highly likely that polypeptides encoded by the claimed nucleic acids can be used to treat diseases in which NR10 is implicated, such as leukemia, inflammation, and allergy, or to screen for NR10 inhibitors (e.g., antibodies) useful for treating these diseases.

Indeed, the Examiner appears to acknowledge that NR10 is in fact a hemopoietic receptor, basing his conclusion of lack of credibility on a different theory:

> The lack of credibility does not derive from a disbelief that NR10 is a member of [the hemopoietic receptor] family, but rather a disbelief that NR10 would play a role in essentially every possible place that immune cells can become disregulated (Office Action, at page 7, lines 19-21).

Applicants point out that the mere fact that the specification discloses several possible uses for the NR10 polypeptides does not mean that the claimed nucleic acids have no credible utility. According to MPEP 2107 II, Examination Guidelines for the Utility Requirement,

> An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement (emphasis added).

As discussed above, at least one of the asserted utilities, i.e., treating diseases in which NR10 is implicated, such as leukemia, inflammation, and allergy, is credible. Thus, it is respectfully submitted that the asserted utility for the claimed nucleic acids meets the credibility requirement.

To support the credibility of the utilities asserted in the specification, Applicants previously submitted copies of three articles: Dillon *et al.*, Diveu *et al.*, and Kernebeck *et al.* As discussed in the response and above, Dillon *et al.* proves that NR10.1, NR10.2, and NR10.3 are receptors of cytokines, e.g., IL-31, and involved in inflammatory disease and allergy. Diveu *et al.* describes another IL-31 receptor (GPL), the sequence of which is substantially identical to NR10. According to Diveu *et al.*, IL-31 and GPL are involved in inflammatory diseases. Kernebeck *et al.* describes a family of cytokine receptors and domains conserved among its members, including the above-mentioned WS motif. These references support the credibility of using the soluble extracellular domains of the NR10 polypeptides in treating inflammatory diseases and allergy.

The Examiner countered that the articles were irrelevant since (i) Dillon *et al.* and Diveu *et al.* were published well after the effective filing date of the present application and (ii) Kernebeck *et al.* does not address NR10 protein. See the Office Action, page 8, lines 10-18.

Applicants disagree. MPEP 2124 provides the following guidelines regarding printed publications or references:

> In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism.

In view of the above remarks, it is clear that Dillon *et al.* and Diveu *et al.* show "characteristics and properties of a material," i.e., NR10.1, NR10.2, and NR10.3, and that Kernebeck *et al.* shows "a scientific truism" for a family of cytokine receptors. According to the quote from MPEP 2124, they "need not be available ... before applicant's filing date." Thus, Applicants submit that all three papers are relevant to establishing that Applicants' assertions of utility were correct, and respectfully request that they be considered.

To further support credibility of the asserted utilities, Applicants submit herewith four articles that concern a receptor, IL-6 receptor, that is highly homologous to NR10:

Sato *et al.*, "Reshaping a human antibody to inhibit the interleukin 6-dependent tumor cell growth." Cancer Research 53:851-856, February 1993;

Matsuno *et al.*, "Treatment of rheumatoid synovitis with anti-reshaping human interleukin-6 receptor monoclonal antibody." Arthritis & Rheumatism 41(11):2014-2021, November 1998;

Nishimoto *et al.*, "Improvement in Castleman's disease by humanized anti-interleukin-6 receptor antibody therapy." Blood 95(1):56-61, January 2000 (Nishimoto 2000); and

Nishimoto *et al.*, "Toxicity, Pharmacokinetics, and Dose-Finding Study of Repetitive Treatment with the Humanized Anti-Interleukin 6 Receptor Antibody MRA in Rheumatoid Arthritis. Phase I/II Clinical Study." The Journal of Rheumatology 30(7):1426-1435, 2003 (Nishimoto 2003).

Copies of these four references are included in the Information Disclosure Statement filed herewith.

The references teach that a cytokine receptor can be used to develop antibodies as therapeutic agents for treating a number of immune system disorders in which the cytokine receptor is implicated. Specifically, Sato *et al.* describes use of anti-IL-6 receptor antibodies in inhibiting the growth of multiple myeloma cells. Matsuno *et al.* and Nishimoto 2003 teach that anti-IL-6 receptor neutralization antibodies were used in treating Rheumatoid Arthritis. Nishimoto 2000 describes use of anti-IL-6 receptor neutralization antibodies in treating Castleman's disease.

These four articles support the assertion that specific antibodies against NR10 can be useful for treating a disease in which NR10 is implicated, such as leukemia, inflammation, or allergy. One of ordinary skill would not find such a use to be "incredible." Accordingly, the receptors and nucleic acids encoding NR10 have credible utilities.

For the reasons set forth above, Applicants submit that the Examiner has not established that the logic underlying the asserted utility is "seriously flawed," nor that the facts upon which the assertions are based are "inconsistent with the logic underlying the assertion." Nor has the Examiner established that it is more likely than not that a person skilled in the art would not consider credible the asserted specific and substantial utility. As such, the asserted utility is not only specific and substantial, but also credible. Applicants therefore respectfully request that this rejection be withdrawn.

II. Well-Established Utility

In addition to the above-discussed asserted utility that is specific, substantial and credible, the invention has a well-established utility. The Utility Training Materials defines "well-established utility" as "a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art" (at page 7).

As discussed above, the nucleic acids of claim 1 encode hemopoietin factor receptor proteins. This fact is not in dispute. It is well known in the art that hemopoietin factors (also known as cytokines) are involved in systemic humoral regulation of hemopoietic or immune functions. See, e.g., the specification, pages 1-2, bridging paragraph. The utility of cytokine receptors in general without question qualifies as "well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art." Also, as set forth above in Part I, one skilled in the art would appreciate that the utilities of the invention are "specific, substantial, and credible." Accordingly, the nucleic acids of claim 1 possess well-established utilities.

Claim 2 is directed to an isolated nucleic acid containing a sequence encoding NR10.1, NR10.2, or NR10.3, or a fragment thereof. Claim 20 is drawn to an isolated nucleic acid containing a coding region of SEQ ID NO:1, 3, or 16, corresponding to NR10.1, NR10.2, and NR10.3, respectively. Claim 24 covers an isolated nucleic acid comprising a nucleotide sequence encoding a protein that comprises the amino acid sequence of SEQ ID NO:2, 4, or 17, with a single amino acid replacement, deletion, insertion, or addition, where the protein binds to a hematopoietin factor. For the same reasons as set forth above regarding claim 1, these claims also meet the utility requirement. So do claims 3-8, 21-23, and 25-27, which are drawn to vectors or transformants containing the nucleic acid of claim 1, 2, 20, or 24.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-8 and 20-27 for lack of enablement, contending that these claims do not meet the utility requirement, so one of skill in the art would not know how to use the claimed invention. See page 9, lines 1-4, of the Office Action. As set forth above, all of

the claimed compositions do possess patentable utilities. Thus, withdrawal of the enablement rejection is respectfully requested.

CONCLUSION

Applicants submit that all of the pending claims are in condition for allowance, and such action is respectfully requested.

The extension fee in the amount of $1020 is being paid concurrently on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to deposit account 06-1050, referencing attorney docket 14875-096001.

Respectfully submitted,

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